

JAN 22 2010

## 510(k) Summary

## ADMINISTRATIVE INFORMATION

Manufacturer Name: X-spine Systems, Inc.  
452 Alexandersville Rd.  
Miamisburg, OH 45342

Telephone (937) 847-8400  
FAX (937) 847-8410

Official Contact: David Kirschman, MD  
Chief Medical Officer

## DEVICE NAME

Trade/Proprietary Name: ACP4™ Spinal Implant System

Classification Name: Spinal Intervertebral Body Fixation Orthosis

Common Name: Cervical plating system

## ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X spine Systems; Inc. is 9063903.

## DEVICE CLASSIFICATION

FDA has classified anterior cervical plating devices as a Class II (21 CFR 888.3060). The product code for Spinal Intervertebral Body Fixation Orthosis is KWQ. These device classifications are reviewed by the Orthopedic Devices Branch.

## INTENDED USE

### Indications for Use:

The X-Spine ACP4 System is intended for anterior screw fixation to the cervical spine (C2-C7 inclusive).

The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fractures or dislocations),
- Tumors,
- Deformity (defined as kyphosis, lordosis, or scoliosis)
- Pseudoarthrosis, and/or
- Failed previous fusions.

## DEVICE DESCRIPTION

The X-Spine ACP4 System includes titanium alloy anterior cervical plates and bone screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine, levels C2 to C7. The implant components are provided clean and non-sterile.

## EQUIVALENCE TO MARKETING PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the ACP4 Spinal Implant System is substantially equivalent in indications and design principles to predicate devices.

## PERFORMANCE DATA

Biomechanical testing indicates that the ACP4 system is capable of performing in accordance with its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

JAN 22 2010

X-Spine Systems, Inc.  
% David Kirschman, M.D.  
Chief Medical Officer  
452 Alexandersville Road  
Miamisburg, Ohio 45342

Re: K092360

Trade/Device Name: ACP4™ Spinal Implant System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: Class II  
Product Code: KWQ  
Dated: January 15, 2010  
Received: January 19, 2010

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Page 2 – David Kirschman, M.D.

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Dave Kirschman

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson  
Director Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K092360

Device Name: ACP4™ Spinal Implant System

#### Indications for Use:

The X-Spine ACP4 System is intended for anterior screw fixation to the cervical spine (C2-C7 inclusive). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

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- Tumors,
- Deformity (defined as kyphosis, lordosis, or scoliosis)
- Pseudoarthrosis, and/or
- Failed previous fusions.


Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K092360